

Amendments to the Claims: This listing of claims will replace all prior versions, and listings, of claims in the application

Listing of Claims:

1. (Currently amended) An aqueous formulation comprising, on a gram per ml (w/v) basis:

- a. ~~a block copolymer;~~
- b. ~~a polyethylene glycol (PEG); and~~
- c. ~~1-2 % 2,6-diisopropylphenol;~~
- d. ~~propylene glycol; and~~
- e. water and up to 15% excipients, said excipients consisting essentially of, on a gram per ml total formulation basis, up to 6% polyethylene glycol (PEG), up to 10% of a block copolymer, namely poloxamer 188, and optionally, one or more pH modifiers, stabilizers, or tonicity modifiers, said formulation comprising an aqueous solution clear to the naked eye.

2-9. (Canceled)

10. (Canceled)

11. (Amended) The formulation of claim ~~10~~ 1, wherein the total amount of said block copolymer is from about 5% to about 10% (w/v) of said formulation.

12. (Amended) The formulation of claim ~~11~~ 1, wherein the total amount of said block copolymer is from about 6% to 8% (w/v) of said formulation.

13. (Canceled)

14. (Canceled)

15. (Canceled)

16. (Canceled)

17. (Canceled)

18 (Canceled)

19. (Canceled)

20. (Amended) The formulation of claim ~~19~~ 1, wherein the amount of 2,6-diisopropylphenol is about 1% (w/v) of said formulation.

21. (Canceled)

22. (Canceled)

23. (Amended) The formulation of claim ~~22~~ 1, wherein the total amount of PEG is less than about 5% (w/v) of said formulation.

24. (Amended) The formulation of claim ~~22~~ 1, wherein the total amount of PEG is between about 2% and about 6% (w/v) of said formulation.

25. (Previously presented) The formulation of claim 24 wherein the PEG is between about 2% and 4% of said formulation.

26. (Amended) The formulation of claim ~~25~~ 1, wherein the total amount of PEG is between about 3 and 4% (w/v) of said formulation.

27. (Previously presented) The formulation of claim 1, wherein said PEG is selected from the group consisting of PEG-300, PEG-400, PEG-600, PEG-800, and PEG-1000.

28. (Previously presented) The formulation of claim 27, wherein said PEG is PEG-400.

29. (Amended) The formulation of claim 1, wherein ~~the amount of said excipients include propylene glycol~~ and said propylene glycol is not more than 5% (w/v) of said formulation.

30. (Amended) The formulation of claim 29, wherein the amount of propylene glycol is not more than 2% (w/v) of said formulation.

31. (Amended) The formulation of claim 30, wherein the amount of propylene glycol is 1% ~~or~~ to 2% (w/v) of said formulation.

32. (Amended) The formulation of claim 1, wherein said ~~formulation further comprises~~ excipients include citric acid or a salt thereof.

33. (Amended) The formulation of claim 32, wherein ~~formulation comprises~~ the concentration of said citric acid ~~at a concentration between about in said formulation is in the range of from 2.5 and to 15 mM.~~

34. (Previously presented) The formulation of claim 32, wherein said formulation comprises citric acid in an amount of about 2 mg/ml.

35. (Amended) The formulation of claim 1, wherein ~~said formulation further comprises~~ said excipients include an antimicrobial agent.

36. (Previously presented) The formulation of claim 35, wherein said antimicrobial agent is selected from the group consisting of disodium edetate, metabisulfate, benzyl alcohol, cysteine or a salt thereof, EDTA.

37. (Previously presented) The formulation of claim 36, wherein said antimicrobial agent is benzyl alcohol in the amount of up to 0.5% (w/v) of said formulation.

38. (Canceled)

39. (Amended) The formulation of claim ~~38~~28, wherein poloxamer 188 is present in an amount between 6 and 8% (w/v) of said formulation; PEG-400 is present in an amount between 2 and 4% (w/v) of said formulation; and the excipients include propylene glycol ~~is present~~ in an amount not greater than 2% (w/v) of said formulation; ~~and 2,6-diisopropylphenol is present in an amount between 1 and 2% (w/v) of said formulation.~~

40. (Amended) The formulation of claim ~~28~~38, wherein poloxamer 188 is present in an amount of about 8% (w/v) of said formulation; PEG-400 is present in an amount of about 4% (w/v) of said formulation; propylene glycol is present as

an excipient in an amount of about 1% (w/v) of said formulation; and 2,6-diisopropylphenol is present in an amount of about 1% (w/v) of said formulation.

41. (Amended) The formulation of claim 2838, wherein poloxamer 188 is present in an amount of about 8% (w/v) of said formulation; PEG-400 is present in an amount of about 3% (w/v) of said formulation; propylene glycol is present as an excipient and in an amount of about 1% (w/v) of said formulation; and 2,6-diisopropylphenol is present in an amount of about 1% (w/v) of said formulation.

42. (Amended) The formulation of claim 2838, wherein poloxamer 188 is present in an amount of about 7% (w/v) of said formulation; PEG-400 is present in an amount of about 4% (w/v) of said formulation; propylene glycol is present as an excipient in an amount of about 1% (w/v) of said formulation; and 2,6-diisopropylphenol is present in an amount of about 1% (w/v) of said formulation.

43. (Amended) The formulation of claim 2838, wherein poloxamer 188 is present in an amount of about 7% (w/v) of said formulation; PEG-400 is present in an amount of about 3% (w/v) of said formulation; propylene glycol is present, as an excipient, in an amount of about 1% (w/v) of said formulation; and 2,6-diisopropylphenol is present in an amount of about 1% (w/v) of said formulation.

44. (Amended) The formulation of claim 2838, wherein poloxamer 188 is present in an amount of about 6% (w/v) of said formulation; PEG-400 is present in an amount of about 4% (w/v) of said formulation; propylene glycol is present, as an excipient, in an amount of about 1% (w/v) of said formulation; and 2,6-diisopropylphenol is present in an amount of about 1% (w/v) of said formulation.

45. (Amended) The formulation of claim 2838, wherein poloxamer 188 is present in an amount of about 6% (w/v) of said formulation; PEG-400 is present in an amount of about 4% (w/v) of said formulation; propylene glycol is present, as an excipient, in an amount of about 2% (w/v) of said formulation; and 2,6-diisopropylphenol is present in an amount of about 1% (w/v) of said formulation.

46. (Amended) The formulation of claim 2838, wherein poloxamer 188 is present in an amount of about 6% (w/v) of said formulation; PEG-400 is present in an amount of about 6% (w/v) of said formulation; propylene glycol is present, as an excipient, in an amount of about 1% (w/v) of said formulation; and 2,6-diisopropylphenol is present in an amount of about 1% (w/v) of said formulation.

47. (Amended) The formulation of claim 2838, wherein poloxamer 188 is present in an amount of about 8% (w/v) of said formulation; PEG-400 is present in an amount of about 2% (w/v) of said formulation; propylene glycol is present, as an excipient, in an amount of about 1% (w/v) of said formulation; and 2,6-diisopropylphenol is present in an amount of about 1% (w/v) of said formulation.

48. (Amended) The formulation of claim 2838, wherein poloxamer 188 is present in an amount of about 7% (w/v) of said formulation; PEG-400 is present in an amount of about 2% (w/v) of said formulation; propylene glycol is present, as an excipient, in an amount of about 1% (w/v) of said formulation; and 2,6-diisopropylphenol is present in an amount of about 1% (w/v) of said formulation.

49. (Amended) An aqueous formulation, comprising:
a. ~~a block copolymer in an amount of less than about 10% (w/v) of said formulation;~~
b. ~~a polyethylene glycol in an amount of between about 2% and 4% (w/v) of said formulation~~
c. 2,6-diisopropylphenol; and
d. water, and
e. up to 15% (w/v) excipients, said excipients comprising a block copolymer in an amount of less than about 10% (w/v) of said formulation, a polyethylene glycol in an amount of between about 2% and 4% (w/v) of said formulation, and optionally, one or more pH modifiers, stabilizers, or tonicity modifiers, and the formulation includes no other glycol or alcohol and is transparent.

50. (Amended) The formulation of claim 49, wherein said block copolymer is ~~poloxamer 188~~, present in an amount of between about 5% to about

9% (w/v) of said formulation; and said polyethylene glycol is PEG-400, present in an amount of between about 2% and 4% (w/v) of said formulation.

51. (Previously presented) The formulation of claim 50, wherein poloxamer 188 is present in an amount of about 8% (w/v) of said formulation; PEG-400 is present in an amount of about 4% (w/v) of said formulation; and 2,6-diisopropylphenol in an amount of about 1% (w/v) of said formulation, wherein said formulation is substantially free of propylene glycol.

52. (Previously presented) The formulation of claim 50, wherein poloxamer 188 is present in an amount of about 8% (w/v) of said formulation; PEG-400 is present in an amount of about 3% (w/v) of said formulation; and 2,6-diisopropylphenol is present in an amount of about 1% (w/v) of said formulation, wherein said formulation is substantially free of propylene glycol.

53. (Previously presented) The formulation of claim 50, wherein poloxamer 188 is present in an amount of about 7% (w/v) of said formulation; PEG-400 is present in an amount of about 4% (w/v) of said formulation; and 2,6-diisopropylphenol is present in an amount of about 1% (w/v) of said formulation, wherein said formulation is substantially free of propylene glycol.

54. (Previously presented) The formulation of claim 50, wherein poloxamer 188 is present in an amount of about 7% (w/v) of said formulation; PEG-400 is present in an amount of about 3% (w/v) of said formulation; and 2,6-diisopropylphenol is present in an amount of about 1% (w/v) of said formulation, wherein said formulation is substantially free of propylene glycol.

55. (Previously presented) The formulation of claim 50, wherein poloxamer 188 is present in an amount of about 9% (w/v) of said formulation; PEG-400 is present in an amount of about 2% (w/v) of said formulation; and 2,6-diisopropylphenol is present in an amount of about 1% (w/v) of said formulation.

56. (Previously presented) The formulation of claim 50, wherein poloxamer 188 is present in an amount of 8% (w/v) of said formulation; and PEG-400 is present in an amount of 2% (w/v) of said formulation.

57. (Previously presented) The formulation of claim 50, wherein poloxamer 188 is present in an amount of 7% (w/v) of said formulation; and PEG-400 is present in an amount of 2% (w/v) of said formulation.

58. (Amended) The formulation of claim 49, further comprising, in the excipient portion thereof, citric acid or a salt thereof.

59. (Previously presented) The formulation of claim 58, wherein said formulation comprises citric acid at a concentration between about 2.5 and 10 mM.

60. (Amended) The formulation of claim 49, further comprising, in the excipient portion thereof, an antimicrobial agent.

61. (Previously presented) The formulation of claim 60, where said antimicrobial agent is benzyl alcohol.

62. (Amended) The formulation of claim 1 or claim 49, wherein said formulation further comprises, in the excipient portion thereof, polysorbate.

63. (Amended) The formulation of claim 62, ~~wherein 2,6-diisopropylphenol is present in an amount of about 0.5 to about 2.4 percent (w/v) of said formulation; further including in the excipient portion thereof, polyoxyethylene 20 sorbitan monooleate is present, in an amount of about 0.5 to about 15 percent (w/v) of said formulation; propylene glycol is present in an amount of about 0.5 to about 15 percent (w/v) of said formulation; PEG-400 is present in an amount of about 1 to about 20 percent (w/v) of said formulation; and poloxamer 188 is present in an amount of about 2 to about 15 percent (w/v) of said formulation.~~

64. (Previously presented) The composition of claim 1 or claim 49, wherein said block copolymer is purified poloxamer, wherein said purified poloxamer has a

polydispersity value of between about 5 and 1, about 4 and 1, about 3 and 1, about 2 and 1, or about 1.1 and 1.

65. (Canceled)

66. (Amended) An aqueous formulation, consisting essentially of:

a. a block copolymer in an amount of less than about 10% (w/v) of said formulation;

b. a polyethylene glycol in an amount of between about 2% and about 6% (w/v) of said formulation;

c. 2,6-diisopropylphenol;

d. water;

e. optionally citric acid or a salt thereof; and

f. optionally an antimicrobial agent

said components a, b, e, and f comprising excipients of said formulation, said excipients, in total, not exceeding 15% (w/v) of said formulation, said formulation being clear to the naked eye.

67. (Amended) The formulation of claim 66, wherein said ~~formulation~~ citric acid or a salt thereof comprises citric acid.

68. (Amended) The formulation of claim 66, wherein the excipients of said formulation ~~comprises~~ include an antimicrobial agent.

69. (Canceled)

70. (Canceled)

71. (Amended) A ~~lipid-free~~ microemulsion, ~~comprising~~ consisting essentially of:

a. a block copolymer, namely poloxamer 188;

b. a polyethylene glycol (PEG);

c. 2,6-diisopropylphenol;

d. propylene glycol; and

e. water.

said components a, b, and d comprising excipients and said excipients not exceeding 15% (w/v) of said formulation, said microemulsion being lipid-free and clear.

72. (Amended) An aqueous formulation, ~~comprising~~consisting essentially of:

- a. a block copolymer, namely poloxamer 188 in an amount of less than about 10% (w/v) of said formulation;
- b. a polyethylene glycol in an amount of between about 2% and 4% (w/v) of said formulation;
- c. 2,6-diisopropylphenol; and
- d. water;

said components a and b comprising no more than 15% (w/v) of said formulation, wherein said formulation has an average particle size of less than about 65 nanometers.

73. (Amended) A method of inducing or maintaining anesthesia in a mammal, comprising administering to said mammal an amount of a formulation, as claimed in any one of claims 1, 49, 75 or 66, effective to induce or maintain anesthesia.

74. (Amended) A multi-use container, comprising the formulation as claimed in any one of claims 1, 49, ~~or 66,~~ or 75.

75. (New) A formulation comprising a injectable anesthetic solution, including citric acid and an antimicrobial agent as optional components, said formulation including no more than 15% excipients and comprising, in addition to said optional components, a clear aqueous composition selected from the group consisting of:

- a. 1% propofol, 9% poloxamer 188, 2% PEG 400, and water;
- b. 1% propofol, 8% poloxamer 188, 4% PEG 400, and water;
- c. 1% propofol, 8% poloxamer 188, 4% PEG 400, 1% propylene glycol, and water;

- d. 1% propofol, 8% poloxamer 188, 3% PEG 400, and water;
- e. 1% propofol, 8% poloxamer 188, 3% PEG 400, 1% propylene glycol, and water;
- f. 1% propofol, 7% poloxamer 188, 4% PEG 400, and water; and
- g. 1% propofol, 7% poloxamer 188, 4% PEG 400, 1% propylene glycol, and water.

76. (New) The formulation of claims 1 or 49 wherein said pH modifiers are selected from the group consisting of sodium hydroxide, potassium hydroxide, and hydrochloric acid.

77. (New) An aqueous formulation, comprising:

- a. 2,6-diisopropylphenol; and
- b. water, and
- c. up to 15% (w/v) excipients, said excipients comprising, on a gram per mL total formulation basis, 8% poloxamer 188, 3% polyethylene glycol 400, 1% propylene glycol, 0.2% citric acid monohydrate, a preservative, and sodium hydroxide, wherein said formulation is clear to the naked eye.

78. (New) The formulation of any of claims 1, 49, 66, 71, or 75 having an average particle size of from about 30 to about 75 nanometers.